

REMARKS/ARGUMENTS

The Office Action mailed January 24, 2005, has been received and reviewed. Claims 1-11 and 42-62 are currently pending in the application. Claims 1-11 and 42-62 stand rejected. Applicant has amended claims 1, 42, 57, and 60 and respectfully requests reconsideration of the application as amended herein.

35 U.S.C. § 101 Rejections

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 101 as not being supported by an asserted or established utility. Specifically, the Examiner states that “it is not understood what the specific or substantial utility is of studying a system with non-naturally occurring components.” Applicants note that the utility of the described system is discussed throughout the specification, beginning in the Background section, which discusses use of chimeric receptors that are “used to assess the functions of different sequence regions and to assess the activity of different compounds at a particular receptor.” (Specification at pg. 1, lines 17-32, citing to three reference patents).

Also described is the use of chimeric receptors to assess the functions of different sequence regions on receptors, which descriptions are detailed in the noted studies identifying regions of different guanine nucleotide-binding protein coupled receptors. (Specification at pg. 2, lines 3-9, citing to six reference publications). Also discussed is the use of and ability of the claimed receptors to measure the ability of a compound to affect GABA_bR or mGluR activity. (See, e.g., Specification at pg. 6, lines 27-29).

Finally, the function, use, and utility of the claimed receptors is detailed and corroborated in paragraph 3 of the attached Declaration of Laura L. Storjohann (hereafter “Storjohann Declaration”).

In view of the foregoing arguments, Applicants respectfully request withdrawal of the rejections to claims 1-11 and 42-62 based on 35 U.S.C. § 101.

35 U.S.C. § 112, First Paragraph (Enablement) Rejections

A. Lack of asserted utility

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as not being supported by an asserted or established utility for the reasons set forth above in

relation to the Section 101 rejections. As described in the preceding paragraphs, Applicants note that the utility of the described system is discussed throughout the specification in sufficient detail and clarity to enable of person of skill in the art to use the claimed invention. Additionally, as previously discussed, the function, use, and utility of the claimed receptors is detailed and corroborated in the attached Storjohann Declaration in such a manner as to enable of person of skill in the art to use the claimed invention. (See paragraphs 3 and 4 of Storjohann Declaration).

B. Functionality of intracellular domains

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as not being enabled for functional intracellular domains having as few as 10 residues. As suggested by the Examiner, Applicants submit the Storjohann Declaration confirming that functional receptors having an intracellular domain sequence of as few as 10 amino acid residues in length (as specified in claims 1, 57, and 60) can and have been constructed. (See paragraph 5 of Storjohann Declaration).

C. Use of “any” ligand

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as not providing enablement for the methods of using “any” ligand. Claim 1 has been amended to recite that the “extracellular domain is capable of binding a native CaR, mGluR, or GABA_B ligand.” Independent claims 57 and 60 have likewise been amended to recite that the extracellular domain is capable of binding a native mGluR and GABA_B receptor, respectively. As acknowledged by the Examiner, the specification provides guidance and working examples of chimeric receptors which bind to their native ligands. In view of this disclosure, it is predictable to the artisan how to make such a chimeric receptor. As such, undue experimentation is not required to practice the invention as claimed.

In view of the foregoing arguments, Applicants respectfully request withdrawal of the rejections to claims 1-11 and 42-62 based on 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 112, First Paragraph (Written Description) Rejections

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not adequately described in the specification. Specifically, the Examiner contends that the claims and specification do not indicate which known ligand the receptor is to bind. As previously discussed, Claim 1 has been amended to recite that the “extracellular domain is capable of binding a native CaR, mGluR, or GABA_B ligand”, and claims 57 and 60 have likewise been amended to recite that the extracellular domain is capable of binding a native mGluR and GABA_B receptor, respectively. As acknowledged by the Examiner, the specification provides description and working examples of chimeric receptors which bind to their native ligands. As such, the subject matter of the pending claims relating to the extracellular domain that is capable of binding to native ligands is described in the specification in such a way as to reasonably convey to a skilled artisan that the inventors had possession of the claimed invention at the time the application was filed.

In view of the foregoing arguments, Applicants respectfully request withdrawal of the rejections to claims 1-11 and 42-62 based on 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 112, Second Paragraph Rejections

Claims 1-11 and 42-62 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting an essential step, *i.e.*, any result on the G-protein. Independent claims 1, 57 and 60 have been amended to recite that the G-protein interconverts between a GDP bound and a GTP bound form. Thus, the role of the G-protein has been clarified, per the Examiner’s suggestion. In view of the amendments to the claims, Applicants respectfully request withdrawal of the rejections to claims 1-11 and 42-62 based on 35 U.S.C. § 112, second paragraph.

ENTRY OF AMENDMENTS

The amendments to claims 1, 42, 57, and 60 should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add new matter to the application.

CONCLUSION

Claims 1-11 and 42-62 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicant's undersigned attorney.

Respectfully submitted,



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